DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
FOI m3607on

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

APR 21 2000

WARNING LETTER

CERTIFIED MAIL – RETURN RECEIPT REQUESTED

Eli Gendler, M. D., Ph. D.
Medical Director
Pacific Coast Tissue Bank
2500-19 South Flower Street
Los Angeles, CA 90007

W/L 50-00

Dear Dr. Gendler:

During an inspection of Pacific Coast Tissue Bank conducted January 24th through February 2nd, 2000, our investigators documented violations of Section 361 of the Public Health Service Act and Title 21, Code of Federal Regulations, Part 1270 as follows:

Failure to develop adequate written procedures for all significant steps used in determining the suitability of banked human tissue intended for transplantation as required by 21 CFR §1270.31(a) in that the firm's SOPs allow for confirmatory testing of repeatedly reactive Hepatitis B Surface Antigen donors and supplemental testing of repeatedly reactive Hepatitis B Core Antibody donors as a means of potentially qualifying those donors as suitable for transplantation in violation of 1270.21(h)(1).

Failure to ensure that donor specimens are tested using FDA licensed donor-screening tests in accordance with manufacturer's instructions as required by 21 CFR 1270.21(a) in that you have no assurance that your contract testing facilities are meeting the above requirements.

Failure to follow written procedures for all significant steps used in determining the suitability of banked human tissue intended for transplantation as required by 21 CFR §1270.31(b) in that the firm uses both intake and output volumes when calculating plasma dilutions of a donor; the use of output volumes is not referenced in the firm's SOPs.

Failure to maintain records concurrent with the performance of each significant step required in §1270 in the performance of infectious disease screening as required by 21 CFR §1270.33(a) and 21 CFR §1270.35(b) in that the firm does not completely document the oral interview with the coroner's office regarding autopsy results. The records do not include the date, time, contact person or detailed autopsy results.

Failure to maintain records concurrent with the performance of each significant step required in §1270 in the performance of infectious disease screening as required by 21 CFR §1270.33(a) and 21 CFR §1270.35(d).

The firm does not maintain disposition records of tissues unsuitable for transplantation but that are retained by the firm.

Failure to prepare and follow written procedures for designating and identifying quarantined tissue as required by 21 CFR §1270.31(c) and failure to quarantine tissue until it is disposed of as required by 21 CFR §1270.33(e) in that tissue that has been found unsuitable for transplant but that is retained by the firm is not quarantined or identified as unsuitable for use.

Failure to validate written procedures for prevention of infectious disease contamination or cross-contamination by tissue during processing as required by 21 CFR §1270.31(d) in that you have not validated the cleaning procedure outlined in [redacted].

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that your establishment is in compliance with all requirements of the federal regulations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in further regulatory action without further notice, which may include Order for Retention, Recall and/or Destruction, and/or Injunction.

We acknowledge receipt of your response to the FDA-483, Inspectional Observations dated February 20th, 2000, in which you commit to specific corrective actions. We disagree with your arguments regarding confirmatory and supplementary testing of repeatedly reactive tissues and your interpretation of the preamble to the final rule 21 CFR Parts 16 and 1270. Human Tissues Intended for Transplantation published July 29th, 1997 in the Federal Register. In addition, we are concerned that your apparent disagreement with the need for several provisions of the regulations may influence your ability to achieve and maintain compliance. Please contact this office to arrange a meeting with us to discuss this matter. You may contact the District Director's Office at 949-798-7714 to schedule this meeting.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed.

Your written response should be directed to the Food and Drug Administration, Attention:

Thomas L. Sawyer
Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612

Sincerely,

Acting District Director